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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/402,563	10/05/1999	LEO K. VAN ROMUNDE	KOB10	6102

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BOSTON, MA 02109

EXAMINER
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WU, RUTAO

ART UNIT	PAPER NUMBER
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3639

DATE MAILED: 08/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/402,563	<b>Applicant(s)</b> VAN ROMUNDE ET AL.	
	<b>Examiner</b> Rutao Wu	<b>Art Unit</b> 3639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-10,12-14,16 and 17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-10,12-14,16 and 17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of Claims***

1. In response filed June 09, 2006, the applicant amended claims 1 and 12. Claims 1-3, 5-10, 12-14, 16 and 17 are pending in the application.

### ***Response to Arguments***

2. Applicant's arguments, see page 5, filed June 09 2006, with respect to the rejection(s) of claim(s) 1 and 12 under 35 U.S.C. §102(b) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of U.S. Pat No. 5,583,758 to McIlroy et al.

The applicant amended claim 1 and 12 to recite that generation of forms is in function of the past history and all alternative actions and state that McIlroy et al (U.S. Pat No. 5,583,758) does not teach or suggest such feature. The Examiner respectfully disagrees.

McIlroy et al disclose "the data-collection quires are logically structured so that the guideline user identifies pertinent patient characteristics and is led to an endpoint that is usually one guideline treatment option. However, the endpoint may also be two or more alternative treatments, a pointer to a different guideline or a recommendation for further clinical evaluation before treatment is selected." (col 5: lines 14-20) From the disclosure it is clear that not only one treatment option is given out to the user, other

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alternative treatments, or even alternative evaluation recommendations can also be presented to the user. For alternative treatments or alternative evaluation recommendations to be presented to the user, they must have been recorded before the actual implementation by the user. Although McIlroy et al does not expressly state that the other alternative treatments and recommendation for further clinical evaluation constitute "all alternative actions" however, it is obvious that in the case of medical diagnosis, as is the basis behind McIlroy et al's invention, that all available treatments or alternative evaluation recommendations be available to the user as it could be a matter of life or death situation if the patient is misdiagnosed or mistreated.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1, 7, 10 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Regarding claims 1, 7, 10 and 12, the phrase "and/or" renders the claim indefinite because it is unclear whether the limitation(s) should be taken together ("and") or individually ("or"). See MPEP § 2173.05(d).

### ***Claim Rejections - 35 USC § 103***

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6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-3, 5-10, 12-14, 16 and 17 rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat No. 5,583,758 to McIlroy et al.

As per claims 1, 12, McIlroy, et al discloses:

Method for electronically storing, retrieving and/or modifying records.../computer system for electronically storing...(col. 2, lines 42-47. Col. 11, lines 52-64, where displaying of the file on the screen constitutes the storage of the file or record);

comprising a display unit...(Col. 4, line 54);

an input unit...(col. 4, line 52);

a memory unit...(Col. 4, line 52);

and a processing unit...(Col. 4, line 52);

and involving at least one recorded catalogue of recommended actions.../wherein said memory unit of the computer system comprises at least one recorded catalogue... (Col. 7, lines 45-53, Col. 5, lines 21-45);

and for sequentially steering a process of interrelated actions from said at least one recorded catalogue of recommended actions...(col. 7, line 54-Col. 8, line 22, Col. 2, line 59-Col. 3, line 3);

wherein at least on recorded catalogue of recommended action comprises

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hierarchised sequences of alternative actions.../involving hierarchised sequences of alternative actions... (col. 2, lines 66-Col. 3, line 4 (options), Col. 5, lines 14-20);

wherein said actions comprise sequential procedure steps...(col. 7, line 54-Col. 8, line 22);

wherein for each of said steps the method generates electronic evaluation forms.../wherein said processing unit of the computer is programmed to generate electronic evaluation forms...(Abstract, lines 4-14, Figs 10-17);

hierarchically organized as forms and sub-forms...(col. 11, lines 6-18, from Fig. 10 to Fig. 11);

wherein said evaluation forms comprise a list of recommended actions...(col. 13, lines 6-18, Fig. 16);

information-input requests... (Col. 13, lines 30-44).,

and wherein said generation of evaluation forms is carried out in function of said hierarchised sequences of alternative actions...(col. 3, lines 2-4, Col. 5, lines 21-45);

and in function of the past history of all alternative actions...(col. 5, lines 14-20, 46-61);

From the disclosure it is clear that not only one treatment option is given out to the user, other alternative treatments, or even alternative evaluation recommendations can also be presented to the user. For alternative treatments or alternative evaluation recommendations to be presented to the user, they must have been recorded before the actual implementation by the user. Although McIlroy et al does not expressly state that the other alternative treatments and recommendation for further clinical evaluation

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constitute "all alternative actions" however, it is obvious that in the case of medical diagnosis, as is the basis behind McIlroy et al's invention, that all available treatments or alternative evaluation recommendations be available to the user as it could be a matter of life or death situation if the patient is misdiagnosed or mistreated.

so as to enable transfer of a group of evaluation forms and sub-forms in one operation into one file...(col. 18, line 59-Col. 19, line 8).

As per claims 2, 13, McIlroy, et al discloses:

Wherein said at least one recorded catalogue of recommended actions comprise associated electronic selection algorithms in respect of the hierarchised sequences of alternative actions...(col. 3, line 2-4).

As per claim 3, 14, McIlroy, et al discloses:

Wherein said selection algorithms are integrated in said generated electronic forms...(Figs 10-17).

As per claim 5, 16, McIlroy, et al discloses:

Wherein said evaluation form comprises information from records relevant for a decision-request...(col. 5, lines 56-65).

As per claim 6, 17, McIlroy, et al discloses:

Wherein a record of information entered and used is stored in said memory unit... (col. 4, lines 56-59).

As per claim 7, McIlroy, et al discloses:

Wherein a record of the information and actions entered and used is stored in the memory unit of the purpose of measurement of the effectivity and/or efficiency of effects and/or results of the procedure...(col. 18, lines 16-20).

As per claim 8, McIlroy, et al discloses:

Wherein the method involves a supervising organization for the purpose of quality control and quality improvement...(col. 18, lines 20-22).

As per claim 9, McIlroy, et al discloses:

Wherein the method allows for updating of the recorded catalogue(s) of recommended actions... (col. 10, lines 14-15).

As per claim 10, McIlroy, et al discloses:

Wherein said supervising organization evaluates the effectivity and/or efficiency of effects and/or results based on said records of information and actions used/entered, stored during use of the method, and updates the recorded catalogue(s) of recommended actions in function of said evaluation...(col. 3, lines 21-25).

### ***Conclusion***

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within



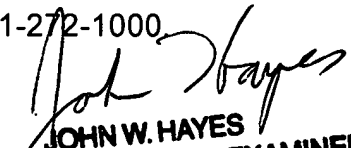
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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rutao Wu whose telephone number is (571)272-3136. The examiner can normally be reached on Mon-Fri 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Hayes can be reached on (571)272-6708. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
JOHN W. HAYES  
SUPERVISORY PATENT EXAMINER